

Echinacea

Oral Liquid

Echinacea Purpurea Root Tincture

Please read this leaflet carefully before using Irish Botanica Echinacea.

It contains important information about this product.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may want to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

- Suffer from a disorder which affects your white blood cells such as agranulocytosis (low white blood cell count due to bone marrow disorders) or leukaemia (blood cell cancer)
- Are having treatment that reduces the response of your immune system e.g. chemotherapy, radiotherapy.
- Have had an organ or bone marrow transplant

What is in this leaflet

1. What is Irish Botanica Echinacea Oral Liquid and what it is used for
2. What you need to know before you take Irish Botanica Echinacea Oral Liquid
3. How to take Irish Botanica Echinacea Oral Liquid
4. Possible side effects
5. How to store Irish Botanica Echinacea Oral Liquid
6. Contents of the pack and other information

Warnings and precautions

- Do not exceed the recommended dosage
- Talk to your doctor or pharmacist before taking this medicine if you have a tendency to allergies such as hives, allergic eczema or asthma.
- If symptoms worsen, or you get a high fever while using this product, or symptoms persist for more than 10 days, consult a doctor or pharmacist

Children and adolescents

Do not give this medicine to children or adolescents under the age of 18 years as it is not known if it is safe to do so.

Other medicines and Irish Botanica Echinacea Oral Liquid:

Do not take this medicine if you are taking any medicines that affect your immune system.

Do not take this medicine if you are already taking another medicine which is affected by alcohol.

Always remember to tell your doctor or pharmacist about any medicines you are taking including herbal medicines such as this one.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, breast-feeding or planning to have a baby as it is not known if it is safe to do so.

Driving and using machines

This product contains alcohol (see below for alcohol content). Overdose of this product may result in alcohol intoxication.

Irish Botanica Echinacea Oral Liquid contains alcohol (ethanol)

This medicinal product contains 45% v/v ethanol (alcohol), i.e. up to 0.9g per dose, equivalent to approximately 23ml beer, or 9ml wine per dose.

Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

1. What this product is and what it is used for

Irish Botanica Echinacea Oral Liquid contains tincture of *Echinacea purpurea* root. It is a traditional herbal medicinal product used in adults to relieve common cold and flu-like symptoms, exclusively based on long-standing use.

2. Before you take this product

Do not take this product if you:

- Are allergic to Echinacea or to plants of the Asteracea (Compositae) family such as daisies, marigolds or artichokes or to any of the other ingredients of this medicine (listed in section 6).
- Are under 18 years of age.
- Suffer from TB (the infection tuberculosis)
- Suffer from Sarcoidosis (connective tissue disease which causes the formation of clumps of cells mainly in the lymph nodes, lungs and liver)
- Suffer from an autoimmune disease such as collagenoses (inflammation of the connective tissue) or multiple sclerosis
- Suffer from HIV, AIDS or another condition which decreases your resistance to infection

3. How to take this product

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Adults and older people:

Take one 2.5ml spoonful in water, three times a day. Start at the first signs of a common cold.

For oral short-term use only.

Do not use this product for more than 10 days.

If symptoms persist for more than 10 days, or worsen, or you get a high fever while using this product, consult a doctor or pharmacist.

Do not exceed the stated dose.

If you take more of this product than you should

If you take more than the recommended dose, speak to a doctor or pharmacist and take this leaflet with you.

Overdose of this product may result in alcohol intoxication and should be treated accordingly. (See Section 2 for alcohol content).

If you forget to take this product

Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this product can cause side effects, although not everybody gets them. Stop taking this product and check with your doctor or pharmacist immediately if any of the following occur:

Allergic reactions such as:

- Skin rash
- Red, itchy skin (hives)
- Blistering of the skin, mouth, eyes or groin (Stevens-Johnson-Syndrome)
- Swelling of the face or skin
- Difficulty breathing
- Asthma and life-threatening allergic reactions (anaphylactic shock).

Echinacea can trigger allergic reactions in patients who have a tendency to develop allergic conditions. Stop taking this medicine immediately if you experience any allergic reaction.

Association with autoimmune diseases has been reported such as:

- Inflammation of the brain and spinal cord (multiple sclerosis)
- Painful lumps on the shins (erythema nodosum)
- Low blood platelet count

- Destruction of blood cells by antibodies (Evans Syndrome)
- Dryness in the mouth and eyes with kidney dysfunction (Sjögren's Syndrome)

The frequency of the above side effects is not known.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel:+353 1 6764971;

Fax:+353 1 6762517

Website: www.hpra.ie;

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing this product

Keep all medicines out of the reach and sight of children.

Do not use this product after the expiry date stated on the bottle and carton. The expiry date refers to the last day of that month

Store in the original packaging. Do not store above 25°C. Return any out of date medicine to your pharmacist who will dispose of it for you.

6. Product Description

Irish Botanica Echinacea is a medium to dark brown, clear oral liquid - a measuring cup, capable of measuring 2.5 ml., is supplied with this product

Ingredients: Each 2.5 ml of oral liquid contains 2.5 ml of tincture from dried *Echinacea purpurea* (L.) Moench, radix (Purple Coneflower, root) (1:3). Extraction solvent: Ethanol 45 % v/v. The product also contains purified water.

This product is available in amber glass bottles of 100ml and 200ml. Not all pack sizes may be marketed.

Manufacturer:

Rutland Biodynamics Ltd, Town Park Farm, Brooke, Rutland LE15 8DG, UK.

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Traditional Herbal Registration Holder

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